

ATTORNEY DOCKET NO. 21085.0044U3  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of )  
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                            )  
Schwiebert *et al.*     ) Art Unit: 1616  
                            )  
Application No. 10/542,555 ) Examiner: John D. Pak  
                            )  
Filing Date: August 29, 2005 ) Confirmation No. 7032  
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For: METHODS AND COMPOSITIONS FOR )  
P2X RECEPTOR CALCIUM ENTRY     )  
CHANNELS AND OTHER CALCIUM     )  
ENTRY MECHANISMS              )

**AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

Sir:

This paper is submitted in response to the Restriction Requirement of January 22, 2007.

In the Restriction Requirement, the Examiner requires Applicant to elect a single invention for prosecution on the merits from one of two patentably distinct inventions. The Examiner contends that these two patentably distinct inventions are those of:

- Group I: Claims 1-3, 12-13, 21-23, and 142-146, drawn to a method of increasing cytosolic  $\text{Ca}^{+2}$  levels in an airway epithelial cell or method of treating an airway disease in a subject comprising contacting cells with  $\text{Zn}^{+2}$  and ATP,  $\alpha,\beta$  methylene ATP, benzoyl benzoyl ATP,  $\text{ATP}\gamma\text{S}$  or AMPPNP.
- Group II: Claims 1-3, 12-13, 21-23, and 142-146, drawn increasing cytosolic  $\text{Ca}^{+2}$  levels in an airway epithelial cell or method of treating an airway disease in a subject comprising contacting cells with  $\text{Zn}^{+2}$  and ivermectin.

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Applicant hereby provisionally elects Group I, as set forth in claims 1-3, 12-13, 21-23, and 142-146 (contacting cells with Zn<sup>+2</sup> and ATP, α,β methylene ATP, benzoyl benzoyl ATP, ATPγS or AMPPNP), with traverse. However, Applicant respectfully requests that the restriction requirement be reconsidered and withdrawn for at least two reasons:

• **The Restriction Requirement does not comply with M.P.E.P § 803**

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Action has not shown that a serious burden would be required to examine all of the pending claims of Groups I and II in the this application. Specifically, M.P.E.P § 803 provides:

If the search and examination of an application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis supplied.*)

Thus, for a restriction to be proper, the Office Action must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. See M.P.E.P § 803.

The Office Action has not shown that the second requirement has been met. Specifically, the Office Action has not shown that it would be a serious burden to search and examine all of the groups together. Indeed, the Office Action has not even alleged that it would be a serious burden to search and examine all of the groups together. Consequently, reconsideration and modification or withdrawal of the restriction is requested.

• **The Action does not meet its burden for establishing lack of unity of invention**

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Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Restriction Requirement does not meet the requisite burden for establishing a lack of unity of invention. Specifically, 37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. PCT Rule 13.2 states that

[T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, the requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features, which define a contribution that the claimed subject matter makes over the prior art. Additionally, MPEP 1850 states that contributions over the prior art “should be considered with respect to novelty and inventive step.”

Applicant respectfully disagrees with the Action’s statement that it has already been established in the original lack of unity requirement of 7/11/2006 that such use of Zn<sup>+2</sup> is not a technical feature that defines a contribution over the prior art. To the contrary, the pending claims are patentable over the cited reference. The Examiner does not reference any specific prior art in the assertion that the claims lack a special technical feature. As it has been previously argued regarding other cited art, the prior art does not teach or suggest that a combination of Zn<sup>2+</sup> and ATP; ivermectin; α, β-methylene-ATP; benzoyl-benzoyl-ATP; ATPγS; or AMPPNP, which would result in a sustained elevation in cytosolic Ca<sup>2+</sup> levels in the cell. This is in stark contrast to the claims as amended, which discloses that there is a sustained elevation in cytosolic Ca<sup>2+</sup> levels in the cell. Thus, the Action has failed to provide any evidence that any disclosure exists

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in the art that would destroy the novelty or inventive step of this common technical feature and thereby destroy the inventive concept. Thus, the Action does not meet the requisite burden for establishing a lack of unity of invention. Accordingly, Applicant submits that all of the pending claims possess unity of invention and, therefore, request reconsideration and modification or withdrawal of the restriction.

Favorable consideration of claims 1-3, 12-13, 21-23, and 142-146 is earnestly solicited.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A credit card payment submitted via EFS Web in the amount of \$230.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(2), and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.  
/Janell T. Cleveland/

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Janell T. Cleveland  
Registration No. 53,848

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

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I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below.			
Name of Person Mailing (Print/Type)	Janell T. Cleveland		
Signature	/Janell T. Cleveland/	Date	November 21, 2007